

REMARKS

Reconsideration of the Office Action mailed October 23, 2003, (hereinafter "instant Office Action"), entry of the foregoing amendments, withdrawal of the rejection of claims 1-3, 7 and 8 are respectfully requested.

In the instant Office Action, claims 1-3, 7 and 8 are listed as pending and claims 1-3, 7 and 8 are listed as rejected.

Applicants gratefully note that the finality of the rejection dated November 13, 2002 is withdrawn.

Claim 2 has been amended to correct a typographical error.

The Examiner has rejected Claim 7 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. Without conceding to the correctness of the Examiner's rejections and for the sole purpose of expediting prosecution of the instant application and to place it in condition for allowance, Applicants have cancelled claim 7 without waiver or prejudice. Therefore, the rejection of Claim 7 under 35 U.S.C. §112, second paragraph, is moot and should be withdrawn.

The Examiner has rejected claims 1-3 and 7 under 35 U.S.C. §103(a) as being unpatentable over Buttle (Exp. Opin. Invest. Drugs (1996), 5(12):1583-1587) and Wilding (BMJ Volume 315, 18 October 1997, pp 997-1000). Applicants respectfully traverse this rejection. Applicants maintain the arguments that were submitted in the Replies mailed October 8, 2002 and April 14, 2003.

Buttle and Wilding do not provide motivation to a person skilled in the art to try the particular combination of sibutramine and orlistat and they do not suggest use of the combination for co-morbid conditions associated with obesity. Buttle and Wilding also do not teach or suggest synergy between sibutramine and orlistat. Neither Buttle nor Wilding teach, suggest or provide motivation for the combination of sibutramine and orlistat in the same patient to treat co-morbid conditions associated with obesity.

Further proof of the unobviousness of the combination of sibutramine and orlistat is found in studies conducted by Dr. David Heal have shown that the combination of sibutramine

and orlistat results in higher than expected weight loss over what would be expected under individual application of either sibutramine or orlistat. In fact, the Declaration by David Heal submitted in the reply filed April 14, 2003 provided evidence of the unobviousness of this combination.

The Examiner comments that the Declaration by David Heal was directed to obesity and the instant application is directed to co-morbid conditions associated with obesity and that Applicants have not provided the necessary nexus between the showing of Dr. Heal's Declaration and the presently claimed subject matter. Applicants respectfully point out the co-morbid conditions being treated with the combination of sibutramine and orlistat are *associated with obesity*. The Declaration by Dr. Heal provides evidence of the effectiveness of the combination of sibutramine and orlistat in treating obesity. Successful treatment of obesity (i.e. weight reduction) will result in successful treatment of the accompanying co-morbid conditions associated with the obesity.

The applicants maintain that taking the prior art as a whole there was no motivation to combine sibutramine and orlistat to treat co-morbid conditions. However, even if the Examiner does not agree that the results in David Heal's declaration demonstrate the unexpected potential for synergy with the combination of the present invention, neither Buttle nor Wilding teaches or suggests the administration of sibutramine and orlistat in the same patient for treatment of co-morbid conditions associated with obesity.

The Examiner newly notes that claim 7 reads on the manufacture of a medicament containing a compound of formula I as "defined" in claim 7 and that the references relied upon do not teach manufacturing method for a medicament containing such compound. In view of Applicants' cancellation of claim 7, this objection is moot.

Based upon the foregoing, Applicants submit that the rejection of claims 1-3 and 7 over Buttle and Wilding under 35 U.S.C. §103(a) is obviated and should be withdrawn.

The Examiner has rejected Claim 8 under 35 U.S.C. §102(e) over Heal et al. (U.S. Patent No. 6,403,641) alleging that Heal et al. teaches the claimed composition. In view of Applicants' cancellation of Claim 8 this rejection has been rendered moot.

The Examiner has rejected Claim 8 under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 5 and 6 of prior U.S. Patent No. 6,403,641 (Heal et al.). In view of Applicants' cancellation of Claim 8 this rejection has been rendered moot.

No fees are due for the instant amendment since the total number of claims after entry of the amendments hereinabove is not more than the total number of claims that Applicants have paid for to date.

Applicants also attach an Information Disclosure Statement and a full copy of the reference *Finer, N. Brit. Med. Bull.*, 53(2), 409-432, (1997) which was cited in the Information Disclosure Statement submitted April 14, 2003. A copy of the abstract only was submitted with the Information Disclosure Statement.

Based upon the foregoing, Applicants believe that claims 1-3 are in condition for allowance. Prompt and favorable action is earnestly solicited.

If the Examiner believes that a telephone conference would advance the condition of the instant application for allowance, Applicants invite the Examiner to call Applicants' agent at the number noted below.

Respectfully submitted,

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Gayle O'Brien

Gayle O'Brien
Agent for Applicants
Reg. No. 48,812

Abbott Bioresearch Center
100 Research Drive
Worcester, MA 01605
(508) 688-8053